

## **REMARKS**

Applicant respectfully requests reconsideration and allowance of all pending claims.

### **I. Status of the Claims**

Claims 1-14 are pending in this application. In this Amendment A, claims 1, 3, 4 and 5 have been amended. Support for these amendments may be found in original claims 1, 3, 4 and 5. Claims 8-10, previously 7-9, are amended to correct an error in numbering. New claims 11-14 are added. Support for these new claims may be found in original claims 1, 3-5 and 8-10. No new matter has been added by way of these amendments.

### **II. Claim Objections**

Applicants note that original claims 7-9 have been renumbered 8-10. By way of this amendment, this objection has been obviated.

### **III. Rejection of Claims under 35 U.S.C. § 112**

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as not enabling for treatment of a mammal suffering from any dermatological condition. Specifically, the Office has stated that Applicants' specification does not reasonably provide enablement for treatment of a mammal suffering from "any dermatologic condition." (Office action of September 22, 2009, page 3). Applicants respectfully submit that independent claims 1, 3, and 4, as amended, and the claims depending thereon do not recite the treatment of any and all dermatological conditions, but rather, a specific, well-defined, set of dermatological conditions, all characterized by oxidative stress. Specifically, claim 1, as amended, recites a method of treatment for a dermatologic condition selected from contact dermatitis, skin irritation, acne, rosacea, and psoriasis. Claims 3 and 4, as amended, each recite a method of treatment for a mammal suffering from a dermatologic condition selected from the group consisting of regulating skin condition, regulating the signs of skin aging or for treating contact dermatitis, skin irritation, acne, rosacea, psoriasis, age-related damage or damage resulting from harmful (UV) radiation or environmental pollution, stress and fatigue. Claim 5, as amended, and new claim 12 recite methods of treatment for a mammal suffering from a dermatologic condition selected from

contact dermatitis, skin irritation, acne, rosacea, and psoriasis. Applicants' specification teaches that each of these claimed dermatologic conditions are diseases characterized by oxidative stress. (Applicants' specification, paragraph [0122]).

The purpose of the enablement requirement, that the specification describe the invention in such terms that one skilled in the art can make and use the claimed invention, is to ensure that the invention is communicated to the interested public in a meaningful way. The information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention. (MPEP § 2164). Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. (MPEP § 2164). The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. (MPEP § 2164.01) The MPEP goes on to teach that the fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation: "The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue." (MPEP § 2164.01, internal citation omitted.) The Federal Circuit has given us a number of factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Applicants respectfully submit that a review of their specification and claims, as amended, shows that they meet the requirements for enablement.

Applicants, in their specification, offer an explanation of how the compounds described and claimed therein may work in treating conditions characterized by oxidative stress. (See, *e.g.*, Applicants' specification, paragraphs [0493] and [0496]). Applicants provide specific methods for validating anti-inflammatory activity (paragraphs [0515]-[0517]) and skin cytoprotective activity (paragraph [0518]). Applicants provide a dosage. (Paragraphs [0521], [0522]). Applicants provide methods of delivery. (Paragraphs [0522]-[0540]). Applicants provide methods for making and characterizing the compounds claimed in their methods of use. (See, paragraphs [0541]-[0681] for preparation and characterization of specific compounds of formula I, and paragraphs [0682]-[0688] for preparation and characterization of compounds of formula III). Examples 41-45 provide tests and results for the claimed compounds and their activity with respect to inhibiting Interleukin-1 $\beta$  induction with an EC<sub>50</sub> of 20  $\mu$ M or less (Example 41); rat paw edema assay (Example 42); mouse ear inflammatory response to topical arachidonic acid (Example 43); skin protection assay (Example 44); and E-selecting cells inflammation assay (Example 45).

Comparing Applicants' teachings with the Wands factors shows that while some experimentation may be necessary, that experimentation is not undue or beyond that which the art typically engages in. The claims, as amended, provide specific guidance with respect to both compounds useful in the claimed methods as well as specific skin conditions that may be treated using these compounds and methods. The level of one of ordinary skill is high. Even if, as the Office suggests, the level of predictability in the art is not very high, the level and complexity of experimentation is not undue if the art typically engages in such experimentation. Furthermore, the inventors provide a great deal of direction, as shown above. The inventors also provide examples, albeit *in vitro*, rather than *in vivo*. However, all that is required under § 112, first paragraph, is a **reasonable** correlation between the disclosed *in vitro* utility and an *in vivo* activity. A rigorous correlation is not necessary where the disclosure of pharmacological activity is reasonable based upon the probative evidence. (MPEP § 2164.02, citing Cross v. Iizuka, 753 F.2d 1040, 1050, 224 USPQ 739, 747 (Fed. Cir. 1985)). As evidenced above, the inventors have provided quite a bit of guidance with respect to the claimed methods of use and compounds used therein. There are working examples that correlate with the claimed methods of use.

Accordingly, Applicants respectfully submit that all pending claims are enabled and respectfully request withdrawal of this rejection.

#### **IV. Rejection of Claims under 35 U.S.C. § 103**

Claims 1, 5, 6, 8 and 9 are rejected under 35 U.S.C. 103(a) as unpatentable over Schulze zur Weische *et al.* (U.S. Published Patent Appl. No. 2003/0206933, hereinafter referred to as “Schulze zur Weische”).

Claim 1, as amended, is generally directed to a method of treating a mammal suffering from a dermatologic condition selected from contact dermatitis, skin irritation, acne, rosacea, and psoriasis. The method includes administering a therapeutically effective amount of a compound of Formula I or a compound of Formula III.

Schulze zur Weische discloses the preparation and use of cosmetic agents, and particularly, 2-furanone derivatives, for caring for and maintaining natural functions of the skin and hair. Specifically, the use of 2-furanone derivatives is taught as providing good properties of treated skin and hair, and in particular, improved combabilities, improved shine, and improved elasticity. (See, Schulze zur Weische, paragraphs [0003] and [0008]).

Applicants respectfully submit that Schulze zur Weische does not teach or suggest every element of Applicants’ claims 1, and amended, and claims 6, 8 and 9<sup>1</sup> depending thereon. Specifically, nowhere in Schulze zur Weische are compounds having the structure of Formula I or Formula III taught or suggested. While Schulze zur Weische teach 2-furanone derivatives, nowhere in Schulze zur Weische is there a suggestion that its derivatives can include a sulfur-containing or phosphorus-containing substituent as required of the X and/or Y substituents of Formulas I and III used in amended claim 1. Furthermore, nowhere in Schulze zur Weische is the treatment of a specific dermatologic condition selected from contact dermatitis, skin irritation, acne, rosacea, and psoriasis taught or suggested. At best, Schulze zur Weische teach the general care and maintenance of skin and hair, and more particularly, teach agents for providing improved combability, improved shine and improved elasticity (see paragraph [0008]).

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<sup>1</sup> Claim 5, as amended, now depends from claim 3, rather than claim 1. As claim 3 is not rejected under 35 U.S.C. § 103(a), claim 5 will not be addressed further in this analysis.

Furthermore, there is no motivation in Schulze zur Weische to modify its 2-furanone derivatives for use in Applicants' claimed methods. Schulze zur Weische teach numerous suitable derivatives for use as cosmetic agents, and as such, why would one skilled in the art, reading Schulze zur Weische have a reason to modify the derivatives? One simply would not, and could not, have such a reason.

Additionally, nothing in Schulze zur Weische teaches or suggests treating dermatologic conditions beyond the use of ordinary cosmetics; that is nowhere in Schulze zur Weische is there a teaching or suggestion of the **treatment of specific conditions** selected from contact dermatitis, skin irritation, acne, rosacea, and psoriasis, as claimed by Applicants. Accordingly, Applicants respectfully submit that claim 1, as amended, as well as claims 6, 8 and 9 dependent thereon, are not obvious in view of Schulze zur Weische. Applicants respectfully request withdrawal of this rejection.

**V. Double Patenting Rejection**

Claims 1-10 are rejected on the ground of nonstatutory obviousness-type double patenting as unpatentable over the claims of U.S. Pat. No. 6,667,330, in view of U.S. Pat. No. 6,653,346. Specifically, along with this Amendment A, Applicants are submitting a Terminal Disclaimer To Obviate Double Patenting Rejection Over U.S. Pat. No. 6,667,330 in view of U.S. Pat. No. 6,653,346.

Accordingly, Applicants respectfully submit that this rejection is moot.

## **CONCLUSION**

In view of the foregoing, Applicant respectfully requests favorable reconsideration and allowance of all pending claims.

The Commissioner is hereby authorized to charge Deposit Account 01-2384 in the name of Armstrong Teasdale LLP for any fees due for the submission of this Amendment A, including the fee for a one-month extension, and/or for the Terminal Disclaimer being filed simultaneously herewith.

Respectfully submitted,

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Via EFS